DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

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MAY 24 2000

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Andre J.H.J. van Rensburg
Managing Director
APS (USA) Ltd.
2100 S.E. 17th Street
Suite 204
Ocala, Florida 34471

Re: Action Potential Stimulation
Therapy Device, K955470

Dear Mr. Van Rensburg:

The Food and Drug Administration (FDA) has reviewed promotional materials for the Action Potential Stimulation Therapy Device (APST). This product is manufactured by Tech Pulse (Pty) Ltd., Pretoria, South Africa and is distributed by APS. Under the Federal Food, Drug, and Cosmetic Act (the Act) this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body.

The APST has been cleared for marketing under section 510(k) of the Act as a Class II Transcutaneous Electrical Nerve Stimulator (TENS), product code 84 GZJ, and is intended for the relief of chronic, acute, and post-traumatic pain.

We have reviewed your web site at the Internet address: http://www.aps-usa.com as well as an APS press release dated March 10, 2000. The claims on the web site and in the press release for the APST device result in a major modification in the intended use of the device as defined in the Title 21, Code of Federal Regulations, Part 807.81(a)(3)(ii) [21 CFR 807.81(a)(3)(ii)]. Such major modifications require the submission of a new 510(k). Representative examples of these modifications include, but are not limited to, the following:

- APS Technologies, developer of the APS pain therapy device, a device capable of safely penetrating human tissue with DC current, thereby stimulating the natural processes of the human nervous system, has reported the findings of the latest research across the world. These finding reveal that the membrane communications, activated by the application of specific electrical fields as achieved by the APS pain

therapy device, may directly promote the following general functions of the body:

- Wound Healing
- Bone Fracture Healing
- Tissue Regeneration (cell proliferation, new capillary formation, inhibition of microbial growth)
- Alleviation of inflammation and pain (lower back pain (sciatica), headache, dysmenorrhea
- Neurological functioning (depression)
- Amelioration of various chronic diseases (asthma, tinnitus)
- Glucose metabolism and energy production (generation of ATP)

- Claims that APST can treat acute and chronic musculoskeletal pain, acute and chronic joint pain, lumbar and cervical pain
- Claims that APST can be used to treat common sport injuries such as disuse atrophy, muscle pain, muscle spasm, elbow pain, and muscle strains and sprains
- Claims that APST can treat pain from occupational injuries, pain from cumulative trauma injuries, and post-operative pain
- Claims that APST impacts the action of neurohormones resulting in several important changes i.e., a decrease in beta-endorphin levels, increase in leucine enkephalin levels, increase in melatonin and normalization of cortisol and serotonin levels, increase in blood circulation due to the anti-inflammatory action of cortisol, and increased mobility

Your web site also includes numerous testimonial statements from patients who have used the APST device and who claim to have derived the following beneficial effects from using the APST therapy: treatment of rheumatoid arthritis, spondylitis of the spine, and the cure of shingles. Such testimonial statements appearing on your web site essentially become your own statements and promote the APST device for unapproved claims. These claims also modify the intended use of the APST device.

Marketing and promotion of the APST therapy device with the above claims is a violation of the law. In legal terms, the APST is adulterated within the meaning of section 501(f)(1)(B) of the Act and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you showing your device to be safe and effective for the claims made. Your product is misbranded under the Act because you failed to submit information showing that your device is substantially equivalent to other device that are legally marketed.

Finally, we note that a portion of your web site lists some of the relevant warnings, precautions, adverse effects, and contraindications for the device. However, this list is incomplete. FDA's Guidance for TENS 510(k) Content (August 1994, copy enclosed) recommends the following

items be included in the labeling of all TENS devices:

Contraindications:

-Any electrode placement that applies current to the carotid sinus (neck) region)
-Any use of TENS on patients who have a demand-type cardiac pacemaker
-Any electrode placement that causes current to flow transcerebrally (through the head)

Warnings:

-The safety of TENS devices for use during pregnancy or birth has not been established
-TENS is not effective for pain of central origin (this includes headache)

Precautions:

-Isolated cases of skin irritation may occur at the site of electrode placement following long-term application

Adverse Reactions:

-Skin irritation and electrode burns are potential adverse reactions

These contraindications, warnings, precautions, and adverse effects should be included in all of your labeling and promotional materials for the APST device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your APST device. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

It is necessary for you to take action on this matter now. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Florida District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Florida District Office (HFR-SE200, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Sincerely yours,

Byron V Arthur

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:
JDP van Zyl
Tech Pulse
Pretoria, SA

Enclosure
Guidance for TENS 510(k) Content